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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,762	01/25/2002	Min Li	9793/93	9551
757	7590	12/13/2004	EXAMINER	
BRINKS HOFER GILSON & LIONE P.O. BOX 10395 CHICAGO, IL 60610			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 12/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/057,762	LI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Mary (Molly) E. Ceperley	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 11-23, 29-42 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9 and 10 is/are allowed.
- 6) ☒ Claim(s) 8, 24-28 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/12/02; 7/25/03; 1/16/04</u>  | 6) <input type="checkbox"/> Other: _____                                    |

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**1)** Applicant's election without traverse of Invention II, claims 8-10, 24-28 and 43, in the reply filed on September 22, 2004 is acknowledged.

Claims 1-7, 11-23, 29-42 and 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions.

The elected claims should be amended to include the variable definitions of claim 1.

**2)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**3)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**4)** Claims 24-28 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope meant to be encompassed by these claims is unclear. It is unclear whether the recited solubility and stability limitations define a subset of the compounds of formula (II) or whether all compounds of formula (II) inherently possess the recited characteristics. For example, if all of the compounds of formula (II) have "a solubility of at least 100 micrograms per milliliter in water at 25 °C", then claim 24 is a duplicate of claim 8 (with the exception of the case wherein R' is H [definition of claim 24 but not claim 8]).

**5)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**6)** Claims 8, 24, 27, 28 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Fryer et al (U.S. 3,819,602).

The Fryer et al compounds of formula VI wherein "E" is a "sulfate" or "phosphate" moiety anticipate the compounds of instant claim 8 wherein "L" is a "heteroalkyl" group and "Y" is " $-\text{SO}_3^-$ " or " $-\text{PO}_3\text{H}^-$ ". See Fryer et al, col. 2, lines 38-61; Examples 20 and 21; the structures of the corresponding HCAPLUS abstract 1970: 55525. The "kit" of instant claim 43 requires, as its sole component, the compound of claim 24; therefore claim 43 is anticipated by the description of the compounds of Fryer et al. The limitations of instant claims 24, 27 and 28 are considered to be inherent characteristics of the compounds of Fryer et al. In claim 8, the preamble method of use characterization of the compound as being a "water-soluble reference standard" does not constitute a limitation on the compound *per se* which is being claimed.

**7)** Claims 8, 24, 27, 28 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (EP 264,797).

The Wang et al compounds of the structure of Fig. 2 wherein " $\text{R}_1$ " is " $\text{RZQ}$ " wherein "R" is "a linking group consisting of from 0 to 20 carbon atoms and heteroatoms", "Z" is " $\text{SO}_2$ " and "Q" is "OH" anticipate the compounds of instant claim 8 wherein "L" is a "heteroalkyl" group and "Y" is " $-\text{SO}_3^-$ ". See Wang et al, Figure 2 and claim 1; the structures of the corresponding MARPAT abstract 110: 91693. The "kit" of instant claim 43 requires, as its sole component, the compound of claim 24; therefore claim 43 is anticipated by the description of the compounds of Wang et al. The limitations of instant claims 24, 27 and 28 are considered to be inherent characteristics of the compounds of Wang et al. In claim 8, the preamble method of use characterization of the compound as being a "water-soluble reference standard" does not constitute a limitation on the compound *per se* which is being claimed.

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**8)** Claims 8, 24, 27, 28 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanehiro et al (MARPAT abstract 118: 101995).

The Kanehiro et al compounds of the structure of formula I wherein "R<sub>1</sub>" is "RZQ" wherein "R" is a "C1-C10 linkage group containing a hetero atom", "Z" is "SO<sub>2</sub>" and "Q" is "OH" anticipate the compounds of instant claim 8 wherein "L" is a "heteroalkyl" group and "Y" is "-SO<sub>3</sub>". See Kanehiro et al, formula I. The "kit" of instant claim 43 requires, as its sole component, the compound of claim 24; therefore claim 43 is anticipated by the description of the compounds of Kanehiro et al. The limitations of instant claims 24, 27 and 28 are considered to be inherent characteristics of the compounds of Kanehiro et al. In claim 8, the preamble method of use characterization of the compound as being a "water-soluble reference standard" does not constitute a limitation on the compound *per se* which is being claimed.

**9)** Claims 9 and 10 are drawn to allowable subject matter.

**10)** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 08, 2004

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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